Appl. No. 09/710,227 Reply to Office Action of March 10, 2005 Attorney Docket No. 16790-6411 (66790/6411)

#### Remarks:

Responsive to the March 10, 2005 Requirement For Additional Information, the Applicant hereby submits that:

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- 1. The Health Resources U.S.A. L.L.C. pamphlet (hereinafter "the pamphlet") disclosed with the August 21, 2001 IDS was generated approximately one (1) month before the filing date of the application (November 10, 2000).
- 2. The pamphlet was not published before the filing date of the application. Accordingly, no applicable publication date exists.
- 3. No known publications, brochures, manuals, or press releases exist that describe the Health Resources U.S.A., L.L.C. as described by the pamphlet and that were generated before the filing date of November 10, 2000.
- 4. Notwithstanding Item 3, the Applicant notes that the August 21, 2001 Information Disclosure Statement disclosed three letters between Health Resources U.S.A., LLC and the Drug Enforcement Program ("DEA") at items AC, AD, and AE.
- 5. An Application for Registration to the DEA that may be potentially relevant to the subject application and entitled Application For Registration by Health Resources U.S.A. LLC. on May 5, 2000 is attached.
- 6. Further to Item 5, a DEA official visited Health Resources U.S.A., LLC circa June 2000 to discuss the application of Item 5.
- 7. A Drug Distributor License Application to the State of Missouri and by Health Resources U.S.A. LLC dated April 25, 2001 is attached.

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Appl. No. 09/710,227 Reply to Office Action of March 10, 2005 Attorney Docket No. 16790-6411 (66790/6411)

- 8. A Drug Distributor (Certificate/License from the State of Missouri issued to Health Resources U.S.A. LLC on June 30, 2001 is also attached.
- 9. No products or services that were the subject of the pamphlet were marketed or developed before November 10, 2000.

The Applicant believes that all of the required information has been supplied. It is also understand that the fee and certification requirements under 37 C.F.R. § 1.97 have been waived for the documents submitted herewith.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided. Favorable action is respectfully requested.

Respectfully submitted,

Robert L. Villhard

Reg. No. 53,725

Thompson Coburn LLP

One US Bank Plaza St. Louis, Missouri 63101

(314) 552-6000

(314) 552-7000 (fax)

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READ INSTRUCTIONS BEFORE COMPLETING	APPLICAT Under Cont	APPLICATION FOR REGISTRATION Under Controlled Substances Act of 1970	GISTRATIC	N <sub>0</sub>	OME 1111	OMB NO. 1117-0012	DEA Form 225 (Nov. 1999)	72
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BUSINESS Administration F IXX Distributor R Administration F IXX H Administration H Administration J XX Importer H Administration J X Importer H Administration	G Researcher G Exporter	2. DRUG SCHEDULES: EX (X all that apply)	Schedule I	Schedule III XX Narcofic Schedule III XX Non Narcofic	Schedule IV	, es	INDICATE HERE IF YOU REQUIRE ORDER FORM BOOKS.	٢
SUPPLY ANY OTHER DEA REGISTRATION NUMBERS FOR ANY CLASS OF BUSINESS AT THE ADDRESS SHOWN ON THIS APPLICATION.	5. MANUFACTURERS ONLY Mark Category and Schedules applicable in the boxes to the (Definitions on reverse of insti	lules the rig instruct	MANUFACT CATEGOI n sheet) A版列		URERS NES Bulk, Synthesizer - Extrador	= (×	ا ج	
				(1 Dosage Form	alabeler			ΨΑ/11
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ALL APPLICANTS MUST ANSWER THE FOLLOWING: (a) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the state or jurisdiction in which you are operating or propose to operate?	OLLOWING: Iribute, dispense, conduct research, c are operating or propose to operate?	research, or otherwise o operate?	e handle the contin	olled substances	in the schedules fo	ır which you ar	e applying under	ECK HERE.
Yes - State License No.					PENDING	N/A		<u>.                                    </u>
Yes - State Controlled Substance No.					PENDING	N/A		7



6. CONTINUED	
Introduction with controlled YES X: NO State (d) Has the applicant ever had a state (e) professional license or controlled state or federal law? YES X: NO substance registration revoked, substance registration revoked, substant denied described.	If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or planmary, has any officer, partner, stockfolder or proprietor been convicted of a criue in connection with controlled as a substance under state or recent laws, or ever surrendered or had a federal controlled.
	revoked, suspended, restlicted or denied, or ever had a state controlled substance registration "X"   X"   X"   NO   X"   YES   X   NO
7. EXPLANATION FOR ANSWERING "YES" TO ITEM(S) 6(b), (c), (d), or (e). Applicants who have answered 'yes' to liem(s) 6(b), (c), (d), or (e) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use a separate sheet and return with application.	e provided below should be used for this purpose. If additional
8. DRUG CODE NUMBERS must coincide with the schedules requested. Listed below are the Drug Code requirements for each business activity:  Analytical Lab - Not required to fail drug codes  Researcher - Schodule I, II, III III bit addition to codes furnished, but manufacture (synthecizenthatractor) applicants MUST Circle Below those 'Basic Classes' of controlled into y  Exporter - Schodule I flux y  Exporter - Schodule I flux y	Feach business activity: préraits MUST Circle Below those 'Besic Classes' of controlled see a separate sheet and return with application.
9. PAYMENT METHOD (X only one) FEES AF	FEES ARE NOT REFUNDABLE
16 435 0	my B. Howley
10. CERTIFICATION MARK THIS BLOCK IF APPLICANT NAMED HEREON IS A FEDERAL, STATE, OR LOCAL GOVERNMENT OPERATED HOSPITAL, INSTITUTION, OR OFFICIAL.  EXEMPTION The undersigned hereby certifies that the applicant named hereon is a lederal, state, or local government operated hospital, institution, or official, and is exempt from the payment of the application fee.	RETURN COMPLETED APPLICATION WITH FEE IN ATTACHED ENVELOPE
Signature of Certifying Official (other then applicant)	MAKE CHECK OR MONEY ORDER
CEO	DRUG ENFORCEMENT ADMINISTRATION
Thirt or type Name of Cerulying Unical Print or Type Title of Certifying Official	UNITED STATES DEPARTMENT OF JUSTICE
Signalure Description (Court lev) CEO May 5, 2000	DRUG ENFORCEMENT ADMINISTRATION CENTRAL STATION
I hereby certify that the foregoing information furnished on this application is true and correct.  Ewing B. Gourley, CEO	WASHINGTON, D.C. 20038-8083
Chief Operating Officer (CEO)	For information, call 1 (800) 862-9539
resident, Dea	see 'r macy act' intomaillen en last page of application.
DEA Form 225 (Nov. 1999) MAKE A COPY FOR YOUR RECORDS	



SEINO. () 944:TED P. 5:ATION TO: MISSUUHI BUARD OF PHARMACY PO BOX 625 JEFFERSON CITY, MISSOURI 65102-0625 (573) 751-0091

DRUG DISTRIBUTOR LICENSE APPLICATION AND/OR CHANGE OF OWNERSHIP

INSTRUCTIONS PLEASE COMPLETE ALL QUESTIONS	FOR OFFICE USE ONLY
Application fee \$250.00 (all fees are non-refundable).	MEDIFORMS SELECTION OF THE SELECTION OF
NEW APPLICATION ☐ CHANGE OF OWNERSHIP FOR A CURRENTLY LICENSE EFFECTIVE DATE OF CHANGE	ED FACILITY DD 90-
2. APPLICANT NAME (CORPORATION, PARTNERSHIP, INDIVIDUAL OWNERSHIP)	
Health Resources USA, L.L.C.	•
3. APPLICANT ADDRESS (STREET, CITY, STATE, ZIP CODE)	
1505 East Trafficway, Springfield, MO 65802	
4. D/B/A NAME - INDICATE NAME OF DISTRIBUTION FACILITY	D/B/A TELEPHONE
Health Resources USA	417 <sub>)</sub> 869–5522
5. D/B/A ADDRESS (STREET, CITY, STATE, ZIP CODE, COUNTY)	
same as above	
6. THE APPLICANT IS (CHECK ONE)Limited Liability Company	IF A CORPORATION, INDICATE STATE OF INCORPORATION
☐ AN INDIVIDUAL ☐ PARTNERSHIP ☐ CORPORATION	
ATTACH CERTIFICATE OF GOOD STANDING ISSUED BY THE MISSOURI SECRETAR THIS FORM ALLOWS YOU TO TRANSACT BUSINESS IN THIS STATE (FOR INSTATI	
7. APPLICANT WILL PLACE THE FOLLOWING INDIVIDUAL AS MANAGER-IN-CHARGE OF THE DI	
FULL NAME MO PHARMACIST LIC. # DATE OF BIRTH	SOCIAL SECURITY NUMBER
Ewing B. Gourley NA 08-25-42	488-44-1598
8. TYPE OF PRODUCTS DISTRIBUTED  LINUMAN VETERINARY CONTROLLED MEDICAL G PRESCRIPTION PRESCRIPTION SUBSTANCES DRUGS DRUGS	DEVICES
IF YOU CHECK THE CONTROLLED SUBSTANCE BOX, YOU MUST ATTACH COPIES OF YOUR STATE & FEDERAL CONTROLL	LED SUBSTANCE LICENSES.
9. FACILITY IS A  WHOLESALER MANUFACTURER REPACKAGER DOTHER (PL	EASE SPECIFY)
10. TYPE OF FACILITIES SERVICED	
	PTOMETRISTS
☑ PHARMACIES ☑ WHOLESALERS ☑ NURSING HOMES ☐ HOSPITALS ☐ AD	VANCED NURSE PRACTITIONERS
11. To the best of your knowledge, have any of the applicant(s) and/or the manager-in-chaever:	arge associated with this license
(A) Been denied, refused, convicted, fined, disciplined or had a drug distributor/ wholesale license revoked for violation of pharmacy, liquor or drug laws, or presently charged with any such violations, in Missouri or any other state?	□ Yes ⊠ No
(B) Been convicted of any felony, or presently charged with the commission of a felony, in Missouri or any other state?	☐ Yes
If you are presently charged with or have been previously convicted of any such violations, has been disciplined, explain in detail. Use separate sheet.	, explain in detail. If your license

May. 10. 2005 2	: 07PM		N	lo. 0944	P. 6
		rmation requested below for the ov ner is a partnership, list the inform			ner is a corporation, list
NAME	TITLE	ADDRESS	TELEPHONE	% OWNED	SOCIAL SECURITY NUMBER
Ewing B. Gourley	CEO	1690 S. Royal Dr.	417-882-7738	37.5	488-44-1598
		Springfield, MO 65809			
Ben E. Balden	Sales Manager	4375 E. University	417-886-4413	37.5	498-42-5630
		Springfield, MO 65809			
Fred Auger	Contract Manager	P.O. Box 590	610-420-810	25.0	194-38-8031
		Chester Springs, PA 194	125		
	-				
					<u> </u>
Provide detailed information	on on a separate attached p	page for any owner/partner/officer t	hat relates to any o	f the circ	umstances below.
Attached detailed	information relates to Item	No.(s): Fred Auger Item	NO. 2.		
None of the follow	wing circumstances have o	ccurred.			
☐ Details have beel	n reported on prior applicat	ion and there has been no change	<b>.</b> .		
Currently hold a direct of Narcotics and Dange	or indirect interest in any ot erous Drugs. If so, list each	her license now in force issued by licensee name and location of pre	the Missouri Board mises.	of Pharm	nacy or Missouri Bureau
Ever held a drug distribution     such a license. If so, list	utor or a pharmacy license teach licensee name and I	from this state or any other state or ocation of premises.	ever had a financia	ıl interest	in any entity which held
Ever made application for of Narcotics and Dange	or a pharmacy or a drug dis rous Drugs or by the licens	stributor license which was denied to sing authority of any other state.	by the Missouri Boa	rd of Pha	rmacy, Missouri Bureau
Ever held a license or h state, or by the licensing	nad a financial interest in a g authority of any other stat	in entity with a pharmacy and/or d te.	rug distributor licen	se which	was disciplined by this
5. Now employ or anticipal the Missouri Board of P	te employing, at the busine harmacy which was discipl	ss seeking licensure, any person w ined or denied, or any person who	ho has at any time has been convicted	held an ir d of any c	nterest in a license from crime.
6. Been employed by any p	person, partnership, or corp	oration that has had a pharmacy ar	nd/or drug distributo	r license	disciplined by this state.

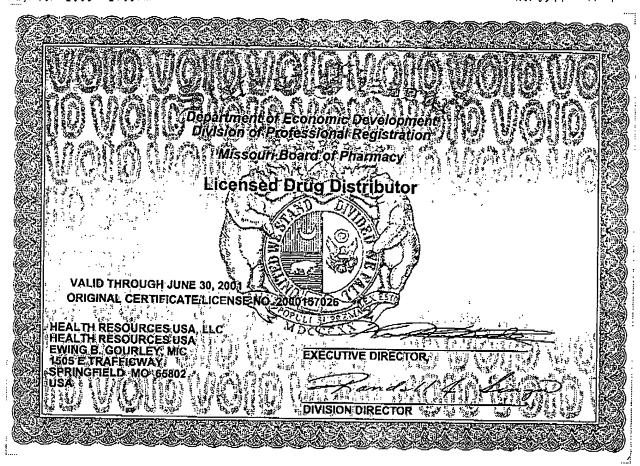
338.185 RSMo. "After the effective date of this act, notwithstanding any other provisions of the law, the Board of Pharmacy shall have access to the records involving an applicant for a license or permit or renewal of a license or permit as provided within this chapter, where the applicant has been adjudicated and found guilty or entered a plea or guilty or noto contendere in a prosecution under the laws of any state or of the United States for any offense reasonably related to the qualifications, functions, or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence or for any offense involving moral turpitude, whether or not sentence is imposed."

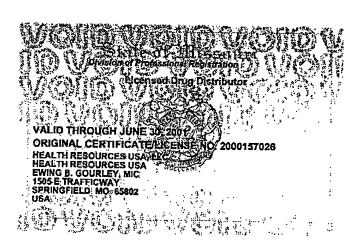
### THIS SECTION MUST BE COMPLETED BY A CORPORATE OFFICER

13. Applicant promises and swears that if a license is issued, such business shall maintain a manager-in-charge and such business will be conducted and operated in full compliance with the pharmacy laws, professional ethics and all other laws of Missouri as long as continued under such license.

I do solemnly swear or affirm that I am the aforementioned applicant and that the statements and representations made in the foregoing application are true and correct. All this I affirm under penalties of perjury.

MOST BE SIGNED IN	SIGNATURE OF AS		calen Ch	50	
PRESENCE OF NOTARY		yun () (B	Euley, CA		
NOTARY PUBLIC EMBOSSER SEAL	STATE OF	$\nu$	Ç .	COUNTY	· · · · · · · · · · · · · · · · · · ·
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	MOTADY DUDY	AE (TYPED OR PRINTED)	1/22/03		ster County
	1	•		My commission	expires Jan 22, 2003
14. TO BE COMPLETED BY	CITECI	A. Royster			
14. TO BE COMPLETED BY	THE MANAGER	I-IN-CHARGE:	_		
I do solemnly swear or affirm requirement of six (6) years e name appearing thereon as r	ducation and/or	experience to qualify	for this position and the	nat I understand the licen	pplication, that I meet the use will be issued with my
MUST BE SIGNED IN	SIGNATURE DE DA	AGER IN CAARGE			
PRESENCE OF NOTARY		and Show	On -		
NOTARY PUBLIC EMBOSSER SEAL	STATE OF			COUNTY	
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	NOTARY PUBLIC SKI		MY COMMISSION		
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	(MITO)	a Layot	1/22/03	STATE OF	MISSOURI
		E (TYPED OR PRINTED)		Webste	er County
	Cristi	A. Royster		My commission expires Jan 22, 2003	
15. List below the names an			out-of-state facilities	owned by the applicant	who also do business in
Missouri. Please provide I	Missouri license i	number.			= === == == ==
NAME OF FACIL	(TY		S (STREET, CITY, STA	TE, ZIP CODE)	LICENSE NO.
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